The Canadian Cervical Cancer Screening Trial of human papillomavirus (HPV) testing versus Pap cytology

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
09/09/2005		[X] Protocol		
Registration date		Statistical analysis plan		
09/09/2005	Completed Condition category	[X] Results		
Last Edited		Individual participant data		
05/01/2010	Cancer			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.mcgill.ca/cccast/

Contact information

Type(s)

Scientific

Contact name

Prof Eduardo L.F. Franco

Contact details

Division of Cancer Epidemiology McGill University 546 Pine Avenue West Montreal Canada H2W 1S6 +1 514 398 6032 eduardo.franco@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-54063

Study information

Scientific Title

Efficacy trial of human papillomavirus (HPV) versus Pap testing for screening cervical cancer precursors: a randomised controlled trial

Acronym

CCCaST

Study objectives

Objectives:

- 1. To compare human papillomavirus (HPV) testing with Pap cytology to detect prevalent and early incident asymptomatic cervical cancers and their high-grade precancerous lesions among women aged 30 69 years who present for their routine cervical cancer screening in Montreal and Newfoundland
- 2. To identify individual, social, and health care delivery variables that influence the performance of the Pap smear and of HPV testing and determine the costs of delivery of those two screening strategies in the two populations chosen for the study

As of 05/01/2010 this record was updated; all details can be found under the relevant section with the above update date. At this point, the target number of participants field was also updated; the initial target number of participants at time of registration was 12,000. However, 14,953 women were assessed for eligibility and invited to participate and 10,154 were randomised into the trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Institutional Review Board of McGill University on the 26th April 2005. Ethics approval has been extended to several additional clinics and institutions involved in the study.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

More information can be found at http://www.mcgill.ca/cccast/

Health condition(s) or problem(s) studied

High-grade cervical intra-epithelial neoplasia

Interventions

Pap testing compared to HPV testing.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Biopsy-proven cervical intraepithelial neoplasia (CIN 2, 3) (high grade intraepithelial lesion [HSIL]) or cancer, ascertained at 6, 12, and 18 months

Secondary outcome measures

Biopsy-proven CIN 1 (low grade intraepithelial lesion [LSIL]) at 18 months.

Overall study start date

26/09/2002

Completion date

31/07/2007

Eligibility

Key inclusion criteria

Current inclusion criteria as of 05/01/2010:

- 1. Women aged 30 to 69 years
- 2. Sought screening tests for cervical cancer in any of 30 family practice or gynaecology clinics in Montreal and St. John's, Canada

Initial inclusion criteria at time of registration:

- 1. Women aged between 30 and 69 years
- 2. Currently attending a colposcopy clinic for evaluation, treatment or follow up of a cervical lesion

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

10,154 randomised into trial

Key exclusion criteria

Current exclusion criteria as of 05/01/2010:

- 1. Currently being followed up for a cervical lesion
- 2. Lacked a cervix
- 3. Pregnant
- 4. Had a history of cervical cancer
- 5. Had undergone Pap testing in the previous year
- 6. Unable to provide consent were excluded (note that this is related also to the ability to understand French or English)

Initial exclusion criteria at time of registration:

- 1. Without a cervix
- 2. Pregnant
- 3. History of cervical cancer
- 4. Known human immunodeficiency virus (HIV) infection
- 5. Mentally incompetent
- 6. Unable to understand French or English
- 7. Refuse to provide an informed consent

Date of first enrolment

26/09/2002

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

Canada

Study participating centre Division of Cancer Epidemiology

Montreal Canada H2W 1S6

Sponsor information

Organisation

McGill University (Canada) - Research Grants Office

Sponsor details

845 Sherbrooke Street West James Administration Bldg., Suite 429 Montreal Canada H3A 2T5 +1 514 398 3996 janine.vasseur@mcgill.ca

Sponsor type

University/education

Website

http://www.mcgill.ca/

ROR

https://ror.org/01pxwe438

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-54063)

Funder Name

Merck-Frosst (Canada) - unrestricted educational grant

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/08/2006		Yes	No
Results article	results	18/10/2007		Yes	No